

a team which includes but is not limited to the physician director of the dialysis facility or center where the patient is presently being treated, in addition to the other personnel listed in paragraph (a)(1) of this section at least every 12 months or more often as indicated by the patient's response to treatment (see § 405.2161(b)(1) and § 405.2170(a)).

(3) The patient, parent, or legal guardian, as appropriate, is involved in the development of the patient's long-term program, and due consideration is given to his preferences.

(4) A copy of the patient's long-term program accompanies the patient on interfacility transfer or is sent within 1 working day.

(b) *Standard: patient care plan.* There is a written patient care plan for each patient of an ESRD facility (including home dialysis patients under the supervision of the ESRD facility; see § 405.2163(e)), based upon the nature of the patient's illness, the treatment prescribed, and an assessment of the patient's needs.

(1) The patient care plan is personalized for the individual, reflects the psychological, social, and functional needs of the patient, and indicates the ESRD and other care required as well as the individualized modifications in approach necessary to achieve the long-term and short-term goals.

(2) The plan is developed by a professional team consisting of at least the physician responsible for the patient's ESRD care, a qualified nurse responsible for nursing services, a qualified social worker, and a qualified dietitian.

(3) The patient, parent, or legal guardian, as appropriate, is involved in the development of the care plan, and due consideration is given to his preferences.

(4) The care plan for patients whose medical condition has not become stabilized is reviewed at least monthly by the professional patient care team described in paragraph (b)(2) of this section. For patients whose condition has become stabilized, the care plan is reviewed every 6 months. The care plan is revised as necessary to insure that it provides for the patients ongoing needs.

(5) If the patient is transferred to another facility, the care plan is sent with the patient or within 1 working day.

(6) For a home-dialysis patient whose care is under the supervision of the ESRD facility, the care plan provides for periodic monitoring of the patient's home adaptation, including provisions for visits to the home by qualified facility personnel to the extent appropriate. (See § 405.2163(e).)

(7) Beginning July 1, 1991, for a home dialysis patient, and beginning January 1, 1994, for any dialysis patient, who uses EPO in the home, the plan must provide for monitoring home use of EPO that includes the following:

(i) Review of diet and fluid intake for indiscretions as indicated by hyperkalemia and elevated blood pressure secondary to volume overload.

(ii) Review of medications to ensure adequate provision of supplemental iron.

(iii) Ongoing evaluations of hematocrit and iron stores.

(iv) A reevaluation of the dialysis prescription taking into account the patient's increased appetite and red blood cell volume.

(v) A method for physician followup on blood tests and a mechanism (such as a patient log) for keeping the physician informed of the results.

(vi) Training of the patient to identify the signs and symptoms of hypotension and hypertension.

(vii) The decrease or discontinuance of EPO if hypertension is uncontrollable.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48952, Oct. 19, 1978; 59 FR 1284, Jan. 10, 1994; 59 FR 26958, May 25, 1994]

§ 405.2138 Condition: Patients' rights and responsibilities.

The governing body of the ESRD facility adopts written policies regarding the rights and responsibilities of patients and, through the chief executive officer, is responsible for development of, and adherence to, procedures implementing such policies. These policies and procedures are made available to patients and any guardians, next of

kin, sponsoring agency(ies), representative payees (selected pursuant to section 205(j) of the Social Security Act and subpart Q of 20 CFR part 404), and to the public. The staff of the facility is trained and involved in the execution of such policies and procedures. The patients' rights policies and procedures ensure at least the following:

(a) *Standard: informed patients.* All patients in the facility:

(1) Are fully informed of these rights and responsibilities, and of all rules and regulations governing patient conduct and responsibilities;

(2) Are fully informed of services available in the facility and of related charges including any charges for services not covered under title XVIII of the Social Security Act;

(3) Are fully informed by a physician of their medical condition unless medically contraindicated (as documented in their medical records);

(4) Are fully informed regarding the facility's reuse of dialysis supplies, including hemodialyzers. If printed materials such as brochures are utilized to describe a facility and its services, they must contain a statement with respect to reuse; and

(5) Are fully informed regarding their suitability for transplantation and home dialysis.

(b) *Standard: participation in planning.* All patients treated in the facility:

(1) Are afforded the opportunity to participate in the planning of their medical treatment and to refuse to participate in experimental research;

(2) Are transferred or discharged only for medical reasons or for the patient's welfare or that of other patients, or for nonpayment of fees (except as prohibited by title XVIII of the Social Security Act), and are given advance notice to ensure orderly transfer or discharge.

(c) *Standard: respect and dignity.* All patients are treated with consideration, respect, and full recognition of their individuality and personal needs, including the need for privacy in treatment. Provision is made for translators where a significant number of patients exhibit language barriers.

(d) *Standard: confidentiality.* All patients are ensured confidential treatment of their personal and medical records, and may approve or refuse re-

lease of such records to any individual outside the facility, except in case of their transfer to another health care institution or as required by Federal, State, or local law and the Secretary for proper administration of the program.

(e) *Standard: grievance mechanism.* All patients are encouraged and assisted to understand and exercise their rights. Grievances and recommended changes in policies and services may be addressed to facility staff, administration, the network organization, and agencies or regulatory bodies with jurisdiction over the facility, through any representative of the patient's choice, without restraint or interference, and without fear of discrimination or reprisal.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 51 FR 30362, Aug. 26, 1986; 52 FR 36934, Oct. 2, 1987]

§ 405.2139 Condition: Medical records.

The ESRD facility maintains complete medical records on all patients (including self-dialysis patients within the self-dialysis unit and home dialysis patients whose care is under the supervision of the facility) in accordance with accepted professional standards and practices. A member of the facility's staff is designated to serve as supervisor of medical records services, and ensures that all records are properly documented, completed, and preserved. The medical records are completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information.

(a) *Standard: medical record.* Each patient's medical record contains sufficient information to identify the patient clearly, to justify the diagnosis and treatment, and to document the results accurately. All medical records contain the following general categories of information: Documented evidence of assessment of the needs of the patient, whether the patient is treated with a reprocessed hemodialyzer, of establishment of an appropriate plan of treatment, and of the care and services provided (see § 405.2137(a) and (b)); evidence that the patient was informed of the results of the assessment described in